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## NOTICE OF ALLOWANCE AND FEE(S) DUE

26813 7590 02/17/2004  
MUETING, RAASCH & GEBHARDT, P.A.  
P.O. BOX 581415  
MINNEAPOLIS, MN 55458

EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/17/2004

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/813,345      | 03/20/2001  | Derek David Smith    | 180.0002 0102       | 2898             |

TITLE OF INVENTION: METHODS FOR INHIBITING CGRP BINDING

| APPLN. TYPE    | SMALL ENTITY | ISSUE FEE | PUBLICATION FEE | TOTAL FEE(S) DUE | DATE DUE   |
|----------------|--------------|-----------|-----------------|------------------|------------|
| nonprovisional | YES          | \$665     | \$300           | \$965            | 05/17/2004 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

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If the SMALL ENTITY is shown as NO:

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

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**Complete and send this form, together with applicable fee(s), to: Mail**

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26813 7590 02/17/2004

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|--------------------|
| (Depositor's name) |
| (Signature)        |
| (Date)             |

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**TITLE OF INVENTION: METHODS FOR INHIBITING CGRP BINDING**

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| EXAMINER    | ART UNIT | CLASS-SUBCLASS |
|-------------|----------|----------------|
| JIANG, DONG | 1646     | 530-326000     |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

|   |       |
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| 1 | _____ |
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(A) NAME OF ASSIGNEE

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Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

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(Authorized Signature)

(Date)

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

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| MUETING, RAASCH & GEBHARDT, P.A.<br>P.O. BOX 581415<br>MINNEAPOLIS, MN 55458 |             |                      | JIANG, DONG         |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1646                |                  |
| DATE MAILED: 02/17/2004  |             |                      |                     |                  |

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

**Notice of Allowability**

Application No.

09/813,345

Examiner

Dong Jiang

Applicant(s)

SMITH ET AL.

Art Unit

1646

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment E, paper No. 17, filed on 7/18/03.
2. ☒ The allowed claim(s) is/are 21-26, 29-47, 54 and 55 to issue as 2, 7, 3-6, 1, 8-22, 24, 23, and 25-27, respectively.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

**DETAILED OFFICE ACTION**

Applicants amendment to the Sequence Listing filed on 25 November 2003 is acknowledged and entered. The newly submitted CRF is in compliance with the requirements of the sequence rules 37 CFR 1.821 - 1.825.

Currently, claims 21-26, 29-47, 54 and 55 are pending, and under consideration.

**Rejoinder:**

Claims 21-26 and 29 are generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 34 and 35, directed to the species of "Z" group in the formula no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Examiner's Statement for Reasons for Allowance**

The following is an examiner's statement of reasons for allowance: claims 21-26, and 29-47, 54 and 55 of the present invention are directed to a method for inhibiting CGRP binding to CGRP receptors with a composition comprising a CGRP receptor-binding peptide modified with chemical groups (see the formula in the claim 29). Rejections of claims 54 and 55 under 35 U.S.C. 112, first and second paragraphs were made in the final Office Action for the recitation of "Z is a vasoactive peptide" in claim 54, and the recitation of "Z is an antagonist of human CGRP" in claim 55, based on that an antagonist of CGRP cannot be vasoactive. Applicants

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argument in the response to the Office Action, filed on 18 July 2003 (paper No. 17) has been fully considered. At page 5 of the response, Applicants argue that Gardiner et al. (*Biochem. Biophys. Res. Commun.*, 1990, 171: 938-943) teaches an antagonist of human  $\alpha$ -CGRP,  $\alpha$ -CGRP (8-37), which can cause an increase in mean arterial blood pressure, together with renal, mesenteric and hindquarters vasoconstrictions. This argument is persuasive as the prior art reference indicates that an antagonist of CGRP can also be vasoactive, such as vasoconstriction. Accordingly, the rejections of claims 54 and 55 are withdrawn.

**Conclusion:**


Claims 21-26, 29-47, 54 and 55 are allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
2/10/04